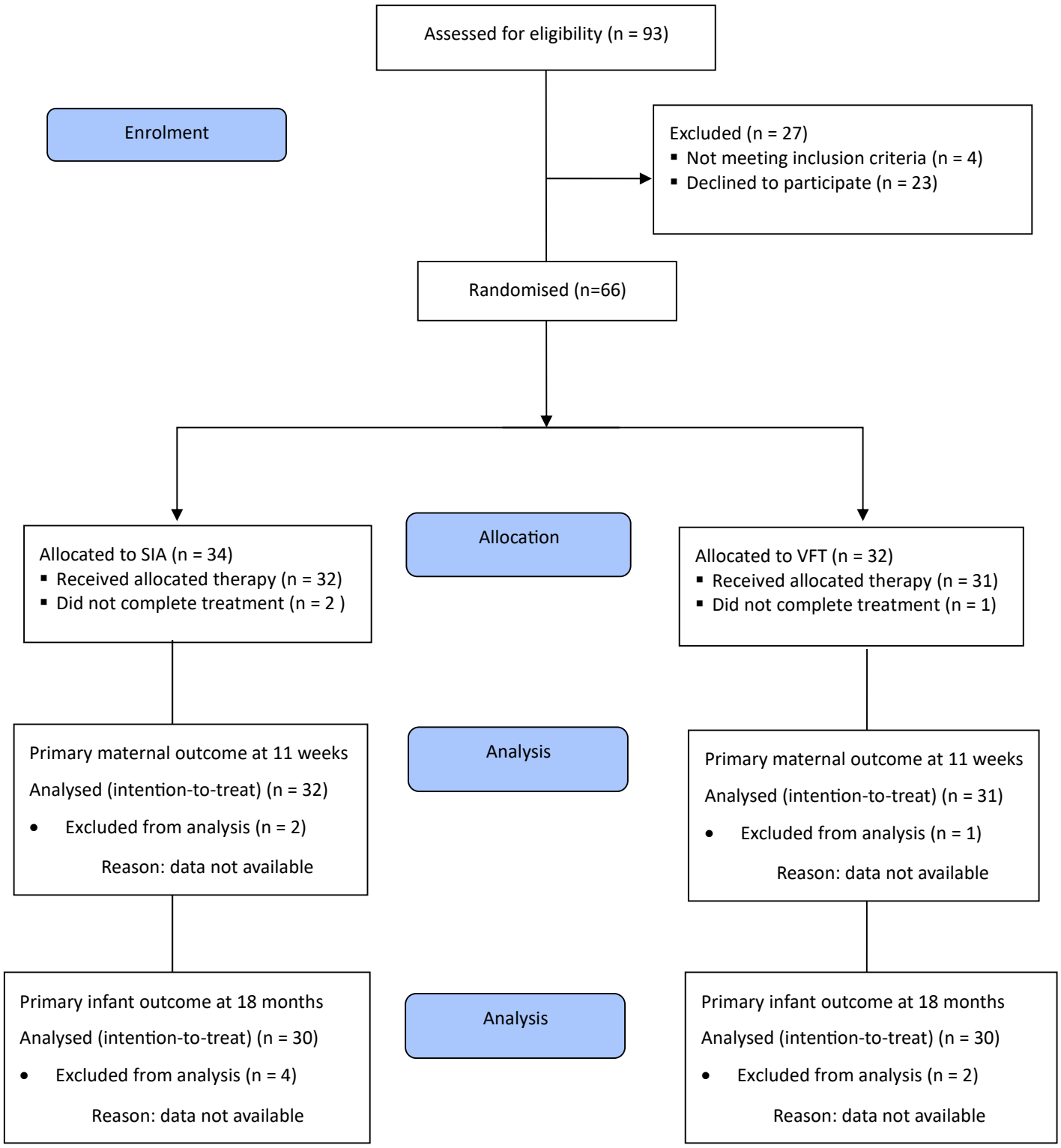
Participant Flow



Baseline Characteristics

		SIA (N = 34)	VFT (N = 32)	Total (N = 66)
Ethnicity; n (%)				
	White - British	28 (82)	26 (81)	54 (82)
	White - Other	4 (12)	5 (16)	9 (14)
	Black or Black British - African	1 (3)	0 (0)	1 (2)
	Asian or Asian British - Indian	1 (3)	1 (3)	2 (3)
Mother's age in years; mean (SD)		33.3 (4.7)	31.1 (6.1)	32.2 (5.5)
Baby's age in weeks; mean (SD)		3.1 (1.5)	2.8 (1.1)	2.9 (1.3)
Birthweight in grams; mean (SD)		3553 (475)	3457 (474)	3506 (473)
Gestation in weeks; mean (SD)		39.8 (1.3)	39.6 (1.4)	39.7 (1.4)
HADS score; mean (SD)		8.3 (4.3)	9.5 (6.7)	8.9 (5.6)
PAC-Q score; mean (SD)				
	Child self confidence*	176 (101)	145 (98)	161 (100)
	Self-blame*	167 (126)	113 (120)	140 (125)
	Growth through challenge**	472 (189)	439 (210)	456 (199)
	Perceived manageability**	459 (39)	461 (58)	460 (49)
	Impact of treatment*	219 (84)	204 (94)	212 (89)
PDS ; mean (SD)		8.9 (8.0)	7.9 (11.1)	8.4 (9.6)

Hospital Anxiety and Depression Scale (HADS)
Parental Appraisal of Cleft Questionnaire (PAC-Q)
Post-traumatic Stress Diagnostic Scale (PDS)

Primary outcome measures

1. **Maternal sensitivity** in face to face interaction with the infant immediately following treatment (when infant aged 11 weeks and prior to lip cleft repair), measured using the Global Rating Scale dimension of sensitivity.

Variable	***Mean SIA (n = 32)***	***Mean VFT (n = 31)***	***Difference (95% CI)***	***p-value^***
Treatment	*Unadjusted analysis*			

	VFT vs SIA	*3.38 (3.07 to 3.68)*	*3.39 (3.08 to 3.70)*	*0.01 (-0.42 to 0.44)*	*0.956*
Treatment		*Adjusted analysis**			
	VFT vs SIA	*3.36 (3.06 to 3.67)*	*3.39 (3.09 to 3.70)*	*0.03 (-0.41 to 0.46)*	*0.905*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

2. **Infant cognitive development** at 18 months (assessed by Bayley Scales of Infant and Toddler Development, 3rd edition)

Variable		**Mean SIA (n = 30)**	**Mean VFT (n = 30)**	***Difference (95% CI)***	***p-value^***
Treatment		*Unadjusted analysis*			
	VFT vs SIA	*104.50 (100.90 to 108.1)*	*105.17 (101.56 to 108.77)*	*0.67 (-4.43 to 5.76)*	*0.794*
Treatment		*Adjusted analysis**			
	VFT vs SIA	*104.59 (100.91 to 108.28)*	*105.07 (101.38 to 108.76)*	*0.48 (-4.77 to 5.72)*	*0.855*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

Secondary outcome measures

1. **Maternal gaze**, measured by eye tracking at 11 weeks

		Mean SIA (n = 22)	**Mean VFT (n = 22)**	**Difference (*95% CI)***	*p-value^*
Treatment				*Unadjusted analysis*	
	VFT vs SIA	*96.90 (93.97 to 99.84)*	*93.44 (90.52 to 96.38)*	*-3.46 (-7.60 to 0.69)*	*0.10*
Treatment				*Adjusted analysis**	
	VFT vs SIA	*96.65 (93.73 to 99.57)*	*93.70 (90.78 to 96.63)*	*-2.94 (-7.14 to 1.25)*	*0.163*
	Wilcoxon rank-sum (Mann-Whitney) test			*Z=0.294*	*0.769*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

2. **Maternal imitation** at 11 weeks

Variable	**Mean SIA (n = 32)**	**Mean VFT (n = 31)**	***Difference (95% CI)***	***p-value^***
Treatment			*Unadjusted analysis*	
VFT vs SIA	*19.35 (14.02 to 24.67)*	*14.29 (8.88 to 19.70)*	*-5.06 (-12.65 to 2.53)*	*0.188*
Treatment			*Adjusted analysis**	
VFT vs SIA	*18.88 (13.45 to 24.31)*	*14.77 (9.26 to 20.29)*	*-4.11 (-11.91 to 3.70)*	*0.296*
Wilcoxon rank-sum (Mann-Whitney) test			*Z=1.639*	*0.101*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

3. **Infant attention** (assessed by the Focused Attention Task) at 9 & 18 months. This was split in to two variables; the length of the longest period of attention (attention to toys) and the average length time of attention periods.

Analysis of attention to toys as an outcome variable

Time point	***Variable***	***Mean SIA (n = 30)***	***Mean VFT (n = 31)***	***Difference (95% CI)***	***p-value^***
9 months	*Treatment*			*Unadjusted analysis*	
	VFT vs SIA	*77.23 (72.45 to 82.02)*	*76.48 (71.77 to 81.18)*	*-0.76 (-7.47 to 5.96)*	*0.822*
	Treatment			*Adjusted analysis**	
	VFT vs SIA	*77.30 (72.27 to 82.34)*	*76.41 (71.46 to 81.36)*	*-0.90 (-8.68 to 5.54)*	*0.802*
18 months	*Treatment*			*Unadjusted analysis*	
	VFT vs SIA	*73.21 (67.95 to 78.48)*	*75.70 (70.52 to 80.88)*	*2.49 (-4.90 to 9.88)*	*0.502*
	Treatment			*Adjusted analysis**	

		VFT vs SIA	*73.55 (68.08 to 79.02)*	*75.38 (70.0 to 80.76)*	*1.83 (-5.88 to 9.55)*	*0.635*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

Analysis of mean play duration (i.e. the average length time of attention periods) as an outcome variable

Time Point	**Variable**		***Mean SIA (n = 30)***	***Mean VFT (n = 31)***	**Difference *(95% CI)***	*p-value^*
9 months	*Treatment*				*Unadjusted analysis*	
		VFT vs SIA	*4.85 (4.12 to 5.58)*	*4.37 (3.65 to 5.09)*	*-0.48 (-1.51 to 0.54)*	*0.350*
	Treatment				*Adjusted analysis**	
		VFT vs SIA	*4.87 (4.11 to 5.63)*	*4.35 (3.60 to 5.10)*	*-0.52 (-1.59 to 0.55)*	*0.335*
18 months	*Treatment*				*Unadjusted analysis*	
		VFT vs SIA	*7.30 (5.57 to 9.03)*	*7.74 (6.03 to 9.44)*	*0.44 (-1.99 to 2.87)*	*0.721*
	Treatment				*Adjusted analysis**	
		VFT vs SIA	*7.45 (5.69 to 9.21)*	*7.59 (5.86 to 9.31)*	*0.14 (-2.34 to 2.62)*	*0.910*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

4. **Infant emotion regulation** (assessed by the LAB-TAB) at 9 & 18 months. This was split into two variables (distress and latency to distress). The distress variable was categorical (no distress, late distress, early distress. While the latency to distress was a time in seconds.

Analysis of latency category (distress) as an outcome variable

Time point	***Variable***		***Odds Ratio (95% CI)***	***p-value^***
9 months	*Treatment*		*Unadjusted analysis*	
		VFT vs SIA	*1.74 (0.66 to 4.54)*	*0.261*
	Treatment		*Adjusted analysis**	
		VFT vs SIA	*1.60 (0.59 to 4.30)*	*0.355*

18 months	*Treatment*		*Unadjusted analysis*	
		VFT vs SIA	*1.0 (0.26 to 3.87)*	*0.99*
	Treatment		*Adjusted analysis**	
		VFT vs SIA	*0.97 (0.23 to 4.01)*	*0.962*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

Analysis of latency to distress (in seconds) as an outcome variable

Time point	***Variable***		***Geometric Mean SIA (n = 12)***	***Geometric Mean VFT (n = 19)***	***Geometric Mean Ratio (95% CI)***	***p-value^***
9 months	*Treatment*				*Unadjusted analysis*	
		VFT vs SIA	*16.93 (8.71 to 32.89)*	*17.81 (10.50 to 30.19)*	*1.05 (0.45 to 2.46)*	*0.904*
	Treatment				*Adjusted analysis**	
		VFT vs SIA	*15.21 (7.63 to 30.33)*	*19.05 (11.06 to 32.82)*	*1.25 (0.51 to 3.06)*	*0.607*
Time point	***Variable***		***Geometric Mean SIA (n = 27)***	***Geometric Mean VFT (n = 27)***	***Geometric Mean Ratio (95% CI)***	***p-value^***
18 months	*Treatment*				*Unadjusted analysis*	
		VFT vs SIA	*6.26 (3.88 to 10.08)*	*3.44 (2.10 to 5.65)*	*0.49 (0.25 to 0.97)*	*0.040*
	Treatment				*Adjusted analysis**	
		VFT vs SIA	*6.72 (4.09 to 11.04)*	*3.19 (1.90 to 5.34)*	*0.44 (0.22 to 0.89)*	*0.024*

**Adjusted for baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

5. **Maternal appraisal, mood and trauma** symptoms immediately after treatment and at 9 & 18 months, assessed by means of self-report questionnaires [Hospital Anxiety & Depression Scale (HADS), Post-traumatic Stress Diagnostic Scale (PDS)] and Parental Appraisal of Cleft Questionnaire (PAC-Q).

Analysis of HADS and PDS as an outcome variables at 11 weeks, 9 and 18 months

Time point	*Variable*		*Mean SIA (n = 32)*	*Mean VFT (n = 31)*	*Difference (95% CI)*	*p-value^*
11 weeks	*Treatment*		*HADS*			
		VFT vs SIA¥	*8.15 (6.64 to 9.66)*	*8.04 (6.48 to 9.60)*	*-0.11 (-2.30 to 2.07)*	*0.917*
		*VFT vs SIA**	*8.11 (6.56 to 9.66)*	*8.08 (6.48 to 9.68)*	*-0.03 (-2.30 to 2.23)*	*0.976*
	Treatment		*PDS*			
		VFT vs SIA¥	*5.30 (3.42 to 7.18)*	*4.48 (2.54 to 6.43)*	*-0.81 (-3.52 to 1.90)*	*0.550*
		*VFT vs SIA**	*5.15 (3.40 to 6.91)*	*4.64 (2.82 to 6.45)*	*-0.52 (-3.07 to 2.03)*	*0.686*
9 months	*Treatment*		*HADS*			
		VFT vs SIA¥	*7.74 (6.16 to 9.32)*	*8.13 (6.55 to 9.71)*	*0.39 (-1.85 to 2.64)*	*0.726*
		*VFT vs SIA**	*7.83 (6.25 to 9.41)*	*8.04 (6.46 to 9.62)*	*0.21 (-2.06 to 2.48)*	*0.856*
	Treatment		*PDS*			
		VFT vs SIA¥	*4.11 (2.45 to 5.76)*	*3.49 (1.84 to 5.15)*	*-0.61 (-2.95 to 1.73)*	*0.602*
		*VFT vs SIA**	*4.05 (2.44 to 5.67)*	*3.55 (1.93 to 5.16)*	*-0.50 (-2.81 to 1.80)*	*0.663*
18 months	*Treatment*		*HADS*			
		VFT vs SIA¥	*7.84 (5.97 to 9.72)*	*6.89 (4.98 to 8.79)*	*-0.96 (-3.64 to 1.73)*	*0.479*
		*VFT vs SIA**	*7.72 (5.88 to 9.55)*	*7.02 (5.15 to 8.88)*	*-0.70 (-3.36 to 1.95)*	*0.597*
	Treatment		*PDS*			
		VFT vs SIA¥	*2.95 (1.42 to 4.49)*	*2.46 (0.90 to 4.02)*	*-0.49 (-2.68 to 1.69)*	*0.653*
		*VFT vs SIA**	*2.74 (1.36 to 4.12)*	*2.68 (1.28 to 4.08)*	*-0.06 (-2.04 to 1.92)*	*0.948*

¥Adjusted for baseline score

**Adjusted for baseline score, baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

Analysis of PAC-Q as an outcome variable at 11 weeks, 9 and 18 months

Time point	*Variable*	*Mean SIA (n = 32)*	*Mean VFT (n = 31)*	*Difference (95% CI)*	*p-value^*
11 weeks	*Treatment*	*Total child's self confidence*			
	VFT vs SIA¥	*466.6 (446.9 – 486.3)*	*435.7 (415.7 - 455.7)*	*-30.88 (-59.05 - -2.71)*	*0.032*
	*VFT vs SIA**	*468.2 (448.9 - 487.4)*	*433.0 (412.7 - 453.2)*	*-35.16 (-63.38 - -6.94)*	*0.016*
	Treatment	*Total child's self-blame*			
	VFT vs SIA¥	*222.0 (200.0 – 244.0)*	*224.3 (201.9 – 246.6)*	*2.30 (-29.42 – 34.03)*	*0.885*
	*VFT vs SIA**	*218.6 (197.3 – 239.9)*	*227.8 (206.1 – 249.5)*	*9.19 (-21.76 – 40.13)*	*0.554*
	Treatment	*Total growth through*			
	VFT vs SIA¥	*536.1 (500.6 – 571.6)*	*448.4 (412.3 – 484.5)*	*-87.64 (-138.5 - -36.75)*	*0.001*
	*VFT vs SIA**	*532.7 (495.9 – 569.4)*	*451.9 (414.6 – 489.2)*	*-80.79 (-133.87 - -27.72)*	*0.004*
	Treatment	*Total resilience*			
	VFT vs SIA¥	*394.9 (384.0 – 405.9)*	*386.2 (375.0 – 397.3)*	*-8.78 (-24.44 – 6.86)*	*0.266*
	*VFT vs SIA**	*397.1 (386.6 – 407.5)*	*384.0 (373.4 – 394.6)*	*-13.03 (-28.03 – 1.97)*	*0.087*
	Treatment	*Total treatment impact*			
	VFT vs SIA¥	*206.9 (187.0 – 226.9)*	*198.8 (178.5 – 226.9)*	*-8.17 (-36.57 – 20.23)*	*0.567*
	*VFT vs SIA**	*205.9 (185.5 – 226.3)*	*199.8 (179.0 – 220.6)*	*-6.07 (-35.4 – 23.3)*	*0.680*
9 months	*Treatment*	*Total child's self confidence*			
	VFT vs SIA¥	*478.1 (450.2 - 506.0)*	*454.1 (426.6 – 481.5)*	*-24.03 (-63.28 – 15.21)*	*0.225*
	*VFT vs SIA**	*477.3 (448.7 – 505.8)*	*454.9 (426.9 – 483.0)*	*-22.31 (-62.65 – 18.02)*	*0.272*
	Treatment	*Total childs self-blame*			
	VFT vs SIA¥	*198.1 (172.4 – 223.8)*	*234.9 (209.7 – 260.3)*	*36.93 (0.42 – 73.44)*	*0.048*
	*VFT vs SIA**	*196.5 (172.2 – 220.8)*	*236.5 (212.6 – 260.4)*	*40.0 (5.33 – 74.68)*	*0.025*
	Treatment	*Total growth through*			

		VFT vs SIA¥	*501.1 (441.9 – 560.3)*	*423.3 (365.0 – 481.5)*	*-77.8 (-161.24 – 5.64)*	*0.067*
		*VFT vs SIA**	*490.3 (434.4 – 546.2)*	*433.7 (378.8 – 488.6)*	*-56.6 (-135.94 – 22.64)*	*0.158*
	Treatment		*Total resilience*			
		VFT vs SIA¥	*391.4 (377.4 – 405.4)*	*392.8 (379.1 – 406.6)*	*1.42 (-18.17 – 21.01)*	*0.885*
		*VFT vs SIA**	*392.6 (379.4 – 405.9)*	*391.6 (378.6 – 404.7)*	*-1.02 (-19.77 – 17.75)*	*0.914*
	Treatment		*Total treatment impact*			
		VFT vs SIA¥	*194.4 (167.7 – 221.1)*	*184.9 (158.6 – 211.1)*	*-9.5 (-46.98 – 27.91)*	*0.612*
		*VFT vs SIA**	*190.8 (164.2 – 217.4)*	*188.4 (162.2 – 214.6)*	*-2.39 (-39.99 – 35.21)*	*0.899*
18 months	*Treatment*		*Total child's self confidence*			
		VFT vs SIA¥	*456.5 (433.1 – 479.9)*	*447.4 (424.0 – 479.9)*	*-9.12 (-42.28 – 24.05)*	*0.584*
		*VFT vs SIA**	*454.5 (432.8 – 476.2)*	*449.5 (427.7 – 471.2)*	*-5.05 (-36.0 – 25.89)*	*0.744*
	Treatment		*Total childs self-blame*			
		VFT vs SIA¥	*201.6 (176.3 – 227.0)*	*203.1 (177.8 – 228.5)*	*1.51 (-34.79 – 37.81)*	*0.934*
		*VFT vs SIA**	*200.6 (174.6 – 226.6)*	*204.2 (178.2 – 230.2)*	*3.64 (-33.69 – 40.96)*	*0.846*
	Treatment		*Total growth through*			
		VFT vs SIA¥	*525.5 (461.7 – 589.2)*	*458.2 (394.5 – 521.9)*	*-67.19 (-157.59 – 23.21)*	*0.142*
		*VFT vs SIA**	*522.2 (461.4 – 583.0)*	*461.5 (400.7 – 522.3)*	*-60.69 (-147.5 – 26.11)*	*0.166*
	Treatment		*Total resilience*			
		VFT vs SIA¥	*384.7 (372.4 – 397.0)*	*384.1 (371.8 – 396.4)*	*-0.56 (-18.0– 16.87)*	*0.949*
		*VFT vs SIA**	*385.7 (372.9 – 398.4)*	*383.1 (370.4 – 395.9)*	*-2.51 (-20.61 – 15.59)*	*0.782*
	Treatment		*Total treatment impact*			
		VFT vs SIA¥	*178.0 (149.6 – 206.4)*	*178.5 (150.1 – 206.8)*	*0.47 (-39.65 – 40.59)*	*0.981*
		*VFT vs SIA**	*177.9 (148.2 – 207.5)*	*178.6 (148.9 – 208.2)*	*0.71 (-41.50 – 42.91)*	*0.973*

¥Adjusted for baseline score

**Adjusted for baseline score, baby gender, cleft type, mother education, antenatal diagnosis, first biological child, and recruitment centre*

^Two sided p-value <0.05 considered to be significant

Adverse Events

There were no adverse events associated with this study.